

Cracked nipples colonized with *Staphylococcus aureus*: a randomised treatment trial

Submission date 09/12/2002	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 09/12/2002	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 13/10/2014	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Judith Lumley

Contact details
Director
Centre for the Study of Mothers' and Children's Health
La Trobe University
251 Faraday Street
Carlton
Australia
VIC 3053

Additional identifiers

Protocol serial number
Research Ethics Number (La Trobe University): 00/124

Study information

Scientific Title

Acronym

ROBIn (Reduction of Breast Infection) Trial

Study objectives

The aim of our study was to prevent mastitis in breastfeeding women with cracked nipples colonised with *S. aureus*. The hypothesis was that a course of antibiotics would reduce mastitis in breastfeeding women with cracked nipples colonized with *S. aureus*. Participating women were randomised to receive a seven-day course of either an oral antibiotic (flucloxacillin) or identical placebo capsules.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Mastitis (prevention of) in lactating women

Interventions

Women with nipple swab positive for *Staphylococcus aureus* are randomised to receive a seven-day course of:

1. Flucloxacillin 500 mg qid, or
2. Identical placebo capsules

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Flucloxacillin

Primary outcome(s)

Incidence of mastitis in each group in the week following recruitment.

Key secondary outcome(s))

Nipple healing, nipple pain.

Completion date

30/11/2002

Eligibility

Key inclusion criteria

1. Breastfeeding women with at least one damaged nipple
2. English-speaking
3. Live in Melbourne
4. Not allergic to penicillin

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

Not provided at time of registration.

Date of first enrolment

01/11/2001

Date of final enrolment

30/11/2002

Locations

Countries of recruitment

Australia

Study participating centre

Director

Carlton

Australia

VIC 3053

Sponsor information

Organisation

La Trobe University (Australia)

ROR

<https://ror.org/01rxfrp27>

Funder(s)

Funder type

Research council

Funder Name

Medical Research Foundation for Women and Babies, Melbourne (Australia)

Funder Name

Australian National Health and Medical Research Council Public Health scholarship (Australia)

Funder Name

Postgraduate grant, Faculty of Health Sciences, La Trobe University (Australia)

Funder Name

Antibiotics provided by CSL Ltd

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	16/09/2004		Yes	No